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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,419	10/15/2007	Alain H. Curaudeau	249692001700	8347

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,419	CURAUDEAU ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-19,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-19,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9, 11-19, 22 and 23 have been examined on the merits.

Applicants' arguments filed August 19, 2010 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The Examiner is in agreement with the persuasive remarks submitted concerning previously withdrawn claim 22. Claim 22 and new claim 23 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. When considering new matter, the question is whether there is explicit, implicit or inherent disclosure.

MPEP § 2163 states that, "[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., In re Lukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); In re Smith, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads)." Further, the MPEP states, "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." Instant claim 14 is drawn to in addition to photodynamic therapy, at least one non-photodynamic treatment for hyperactive sebaceous gland disorder. Instant claim 16 recites the method to treat hyperactive sebaceous glad disorders "other than acne" wherein the method further comprises at least one non-photodynamic treatment selected from retinoids, oral retinoids, oral contraceptives, anti-androgens, anti-progestins, blue light therapy, laser therapy and combinations thereof (claim 16) and one or more topical retinoids (claim 17). The instant specification recites "For the treatment of acne, the present methods may be combined with other methods of treating acne. Known acne treatments include but are not limited to topical retinoids, oral retinoids, antibiotics (especially topical), oral contraceptives, anti-androgens (especially topical), anti-progestins, blue light therapy, laser therapy, and combinations thereof." (specification, page 6).

Instant claims 14-17 are considered to be new matter because instant claim 1 specifically excludes treatment of acne and the additional non-photodynamic treatment is specifically linked to treatment of acne. There are no examples in the instant specification drawn to additional non-photodynamic treatment for hyperactive sebaceous gland disorder that is not linked to treatment of acne, which is specifically excluded in the instant claims.

This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11-19, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation “and derivatives thereof”, and it is unclear what is, or is not, a derivative. Claims 5 and 6 recite porphyrins, which are derivatives of 5-aminolevulenic acid (see below), and thus renders claim 1 unclear as to what is, or is not, a derivative of 5-aminolevulenic acid.

Claims 5 and 6 recites the limitations "a porphyrin or derivative thereof (line 2 of claim 5) and “a pro-porphyrin, a porphyrin or a combination" (lines 5-6 of claim 6). There is insufficient antecedent basis for this limitation in the claim because it depends from claim 1 which excludes the photosensitizer 5-aminolevulinic acid and derivatives thereof. Kalka et al. (U) teach that protoporphyrin IX is formed endogenously after the

application of the hydrophilic porphyrin precursor γ-aminolevulinic acid (ALA) (page 391, column 2 to page 393, column 1). Applicant has not specifically defined what is meant by "derivatives of 5-aminolevulinic acid" thus the porphyrins, derivatives thereof and proporphyrins are seen as derivatives because they are formed endogenously after application of δ ALA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-13, 18, 19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over QLT Inc. WO 03/039597 A1 (N) and Kalka et al. (J Am Acad Dermatol. Mar. 2000) (U).

QLT Inc. teach a method of treatment of atopic dermatitis (page 15, lines 1-2, claim 13), and psoriasis (page 14, lines 28-30, claim 13) comprising administering a photosensitizing agent and light energy (page 2, lines 10-23). The photosensitizers will absorb radiation in the range of from 400 nm to 800 nm (page 3, lines 14-16) and include green porphyrins (page 3, line 31) such as the preferred BPD-MA (verteporfin) (page 4, lines 15-16) and QLT0074 (lemuteporfin) (page 6, lines 4-7). Addressing instant claim 2, drawn to disorders such as seborrhea, seborrheic dermatitis or sebaceous gland hyperplasia, QLT Inc. teach treatment of psoriasis and atopic dermatitis but is silent with regard to treatment of seborrhea, seborrheic dermatitis or sebaceous gland hyperplasia. However, Kalka et al. teach treatment of disorders such as seborrhea with porphyrins and illumination with blue light (page 403, column 2) and treatment of psoriasis with photodynamic therapy (PDT) using photosensitizers such as BPD-MA (verteporfin) (page 402, column 1). It would have been obvious to one of ordinary skill in art at the time it was made to employ the method of treatment of

hyperactive sebaceous gland comprising administering photosensitizing compositions and exposing the subject to light energy motivated by the teaching of Kalka and QLT Inc. that teach both psoriasis and seborrhea are well known to be treated with porphyrins and light energy. Addressing instant claim 3, drawn to a lipophilic photosensitizer, QLT Inc. teach that BPD-MA is a lipophilic and potent photosensitizer. Conversely, if a substance is lipophilic (fat-loving) then it is by token, hydrophobic, addressing instant claim 4). Addressing instant claims 5 and 6, drawn to a photosensitizer that is inter alia, a porphyrin, QLT Inc. teach that BPD-MA and QLT 0074 are "green porphyrins". Addressing instant claim 7 drawn to the photosensitizer selected from verteporfin lemuteporfin or a combination thereof, QLT Inc. teach that the green porphyrins can be used in combination (page 7, lines 10-17). Addressing instant claim 8, drawn to a viscosity at 20°C of from about 50 cps to about 50000 cps, QLT Inc. teach a viscosity of from about 50 cps to about 50000 cps at 20° C (page 9, lines 24-27). Addressing instant claim 9, drawn to the method wherein excess photosensitizer is removed from the skin prior to application of energy, QLT Inc. teach that the composition is washed after allowing time for the photosensitizer to penetrate the stratum corneum and then irradiated with activation energy at an appropriate wavelength (page 12, line 20 to page 13, line 11). Addressing instant claims 11-13, drawn to repeat of steps i and ii about every 6 months, about every 3 months and not less than about 5 days, QLT Inc. is silent as to how often the treatment method is repeated. However, one having ordinary skill in the art at the time the invention was made would be motivated to repeat the treatment as necessary. Since QLT Inc. teach a

treatment and not a cure, it is prima facie obvious to repeat the treatment as necessary and it is within the purview of the artisan to determine and optimize the period between doses. Regarding the limitations of instant claims 1 and 23, drawn to the amount of light energy at a wavelength capable of activating the photosensitizer (claim 1) or lemuteporfin (claim 23) at a fluence rate between about 0.1 mW/cm2 and 600 mW/cm2, QLT Inc. teach absorption in the range of from 400 nm to 800 nm, typically from 600 nm to 750 nm (page 3, lines 14-16) with a specific example of BPD-MA that absorbs light at about 692 nm wavelength (page 4, lines 15-18). Although QLT Inc. does not teach the wavelength capable of activating the photosensitizer at a fluence rate between about 0.1 mW/cm2 and 600 mW/cm2, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Addressing instant claims 17 and 18 drawn to an energy that is supplied by a light emitting diode device and the device emits red and blue light, Kalka et al. teach that diode lasers are employed to produce red light in the range of 770 to 850 nm (page 395, column 1) and teach that photodynamic

management of dermatologic conditions is simplified by the accessibility of the skin to light application and leaves the option to use any light device with the appropriate spectrum corresponding to the absorption maximum of the photosensitizing compound (page 394, column 2). Further, QLT teaches use of any suitable light source to activate the photosensitizer (page 1, lines 9-14) and teach that photosensitizers generally absorb radiation in the range of from 400 nm (about the range of blue light) to 800 nm (about the range of red light) (page 3, lines 14-16).

A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bod*e 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1619

November 24, 2010

/Andrew D Kosar/
Primary Examiner, Art Unit 1654